AMENDMENTS TO THE CLAIMS

Please amend the claims so that they read as follows:

Claims 1-12 (Canceled)

Claim 13 (Currently Amended): A method for subcutaneously administering a biologically active agent, said method comprising:

(a) providing a biologically active agent which can exist in a native conformational state, a denatured conformational state, and an intermediate conformational state which is reversible to said native state and is conformationally between said native and denatured states; and

(b) exposing said biologically active agent to a complexing perturbant to reversibly transform said biologically active agent to said intermediate state and to form a subcutaneously deliverable supramolecular complex, and

(c) subcutaneously administering said supramolecular complex

said perturbant having a molecular weight ranging from about 150 to about 600 daltons, and having at least one hydrophilic moiety and at least one hydrophobic moiety,

said supramolecular complex comprising said perturbant non-covalently complexed with said biologically active agent; and

said biologically active agent not forming a microsphere with said perturbant;

wherein said perturbant is in an amount effective for subcutaneous delivery of said biologically active agent;

wherein said perturbant is selected from the group consisting of (a) a carboxylic acid having the formula

$R—CO_2H$

wherein R is C_1 to C_{24} alkyl, C_2 to C_{24} alkenyl, C_3 to C_{10} cycloalkyl, C_3 to C_{10} cycloalkenyl, phenyl, naphthyl, (C_1 to C_{10} alkyl)phenyl, (C_2 to C_{10} alkenyl)phenyl, (C_1 to C_{10} alkyl) naphthyl, (C_2 to C_{10} alkenyl)naphthyl, phenyl(C_1 to C_{10} alkyl), phenyl(C_2 to C_{10} alkenyl), naphthyl(C_1 to C_{10} alkyl) and naphthyl(C_2 to C_{10} alkenyl);

R being optionally substituted with C_1 to C_{10} alkyl, C_2 to C_{10} alkenyl, C_1 to C_4 alkoxy, -OH, -SH, $-CO_2R^1$, C_3 to C_{10} cycloalkyl, C_3 to C_{10} cycloalkenyl, aryl, (C_1 to C_{10} alkyl)aryl, aryl(C_1 to C_{10})alkyl, or any combination thereof;

R being optionally interrupted by oxygen, nitrogen, sulfur, or any combination thereof; and

R^1 is hydrogen, C_1 to C_4 alkyl or C_2 to C_4 alkenyl; or

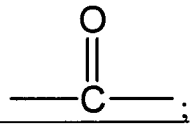
a salt thereof, and

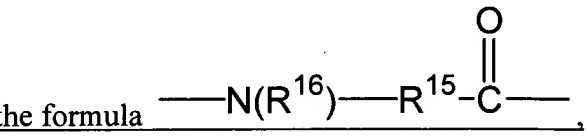
(b) an acylated amino acid having the formula having the formula:

$Ar\text{-}Y\text{-}(R^{14})_n\text{-}OH$

wherein:

Ar is a substituted or unsubstituted phenyl or naphthyl;

Y is  ;

R^{14} has the formula  ,

R^{15} is C_1 to C_{24} alkyl, C_2 to C_{24} alkenyl, phenyl, naphthyl, (C_1 to C_{10} alkyl) phenyl, (C_2 to C_{10} alkenyl) phenyl, (C_1 to C_{10} alkyl) naphthyl, (C_2 to C_{10} alkenyl) naphthyl, phenyl (C_1 to C_{10} alkyl),

phenyl (C_2 to C_{10} alkenyl), naphthyl (C_1 to C_{10} alkyl), and naphthyl (C_2 to C_{10} alkenyl);

R^{15} is optionally substituted with C_1 to C_4 alkyl, C_1 to C_4 alkenyl, C_1 to C_4 alkoxy, -OH, -SH, $-CO_2R^{17}$, cycloalkyl, cycloalkenyl, heterocyclic alkyl, alkaryl, heteroaryl, heteroalkaryl, or any combination thereof;

R^{17} is hydrogen, C_1 to C_4 alkyl or C_2 to C_4 alkenyl;

R^{15} is optionally interrupted by oxygen, nitrogen, sulfur or any combination thereof; and

R^{16} is hydrogen, C_1 to C_4 alkyl or C_2 to C_4 alkenyl;

and n is from 1 to 5, or salt thereof.

Claim 14 (Original): A method as defined in claim 13, wherein said intermediate state has ΔG ranging from about -20 kcal/mole to about 20 kcal/moles relative to said native state.

Claim 15 (Original): A method as defined in claim 13, wherein said biologically active agent is selected from the group consisting of a peptide, a micropolysaccharide, a carbohydrate, a lipid, a pesticide, or any combination of the foregoing.

Claim 16 (Previously Presented): A method as defined in claim 15, wherein said biologically-active agent is selected from the group consisting of human growth hormone, bovine growth hormone, growth hormone-releasing hormone, an interferon, interleukin-II, insulin, heparin, calcitonin, erythropoietin, atrial naturetic factor, an antigen, a monoclonal antibody, somatostatin, adrenocorticotropin, gonadotropin releasing hormone, oxytocin, vasopressin, cromolyn sodium,

vancomycin, desferrioxamine (DFO), low molecular weight heparin, antimicrobials, or any combination of any of the foregoing.

Claims 17 -21 (Canceled)

Claim 22 (Currently Amended): A method as defined in claim 13, wherein said perturbant comprises a carboxylic acid having the formula

$$R—CO_2H$$

wherein R is C_1 to C_{24} alkyl, C_2 to C_{24} alkenyl, C_3 to C_{10} cycloalkyl, C_3 to C_{10} cycloalkenyl, phenyl, naphthyl, (C_1 to C_{10} alkyl)phenyl, (C_2 to C_{10} alkenyl)phenyl, (C_1 to C_{10} alkyl) naphthyl, (C_2 to C_{10} alkenyl)naphthyl, phenyl(C_1 to C_{10} alkyl), phenyl(C_2 to C_{10} alkenyl), naphthyl(C_1 to C_{10} alkyl) and naphthyl(C_2 to C_{10} alkenyl);

R being optionally substituted with C_1 to C_{10} alkyl, C_2 to C_{10} alkenyl, C_1 to C_4 alkoxy, -OH, -SH, $-CO_2R^1$, C_3 to C_{10} cycloalkyl, C_3 to C_{10} cycloalkenyl, ~~heterocyclic having 3-10 ring atoms wherein the hetero atom is one or more atoms of N, O, S or any combination thereof,~~ aryl, (C_1 to C_{10} alkyl)aryl, aryl(C_1 to C_{10})alkyl, or any combination thereof;

R being optionally interrupted by oxygen, nitrogen, sulfur, or any combination thereof; and

R^1 is hydrogen, C_1 to C_4 alkyl or C_2 to C_4 alkenyl; or

a salt thereof.

Claim 23 (Currently amended): A method for subcutaneously administering a biologically active agent comprising:

(a) providing a biologically active agent in an intermediate conformational state non-covalently complexed with a complexing perturbant having a molecular weight ranging from about 150 to about 600 and having at least one hydrophilic moiety and at least one hydrophobic moiety; and

(b) subcutaneously administering said biologically active agent

wherein said intermediate state is reversible to said native state and is conformationally between a native conformational and a denatured conformational state of said biologically active agent and said composition is not a microsphere; and wherein said perturbant is in an amount effective for subcutaneous delivery of said biologically active agent;

wherein said perturbant is selected from the group consisting of (a) a carboxylic acid having the formula

$$R—CO_2H$$

wherein R is C_1 to C_{24} alkyl, C_2 to C_{24} alkenyl, C_3 to C_{10} cycloalkyl, C_3 to C_{10} cycloalkenyl, phenyl, naphthyl, (C_1 to C_{10} alkyl)phenyl, (C_2 to C_{10} alkenyl)phenyl, (C_1 to C_{10} alkyl) naphthyl, (C_2 to C_{10} alkenyl)naphthyl, phenyl(C_1 to C_{10} alkyl), phenyl(C_2 to C_{10} alkenyl), naphthyl(C_1 to C_{10} alkyl) and naphthyl(C_2 to C_{10} alkenyl);

R being optionally substituted with C_1 to C_{10} alkyl, C_2 to C_{10} alkenyl, C_1 to C_4 alkoxy, -OH, -SH, $-CO_2R^1$, C_3 to C_{10} cycloalkyl, C_3 to C_{10} cycloalkenyl, aryl, (C_1 to C_{10} alkyl)aryl, aryl(C_1 to C_{10})alkyl, or any combination thereof;

R being optionally interrupted by oxygen, nitrogen, sulfur, or any combination thereof; and

R^1 is hydrogen, C_1 to C_4 alkyl or C_2 to C_4 alkenyl; or

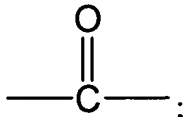
a salt thereof, and

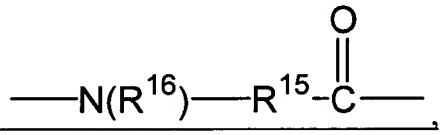
(b) an acylated amino acid having the formula having the formula:

$$Ar\text{-}Y\text{-}(R^{14})_n\text{-}OH$$

wherein:

Ar is a substituted or unsubstituted phenyl or naphthyl;

Y is  ;

R^{14} has the formula  ,

R^{15} is C_1 to C_{24} alkyl, C_2 to C_{24} alkenyl, phenyl, naphthyl, (C_1 to C_{10} alkyl) phenyl, (C_2 to C_{10} alkenyl) phenyl, (C_1 to C_{10} alkyl) naphthyl, (C_2 to C_{10} alkenyl) naphthyl, phenyl (C_1 to C_{10} alkyl), phenyl (C_2 to C_{10} alkenyl), naphthyl (C_1 to C_{10} alkyl), and naphthyl (C_2 to C_{10} alkenyl);

R^{15} is optionally substituted with C_1 to C_4 alkyl, C_1 to C_4 alkenyl, C_1 to C_4 alkoxy, -OH, -SH, $-CO_2R^{17}$, cycloalkyl, cycloalkenyl, heterocyclic alkyl, alkaryl, heteroaryl, heteroalkaryl, or any combination thereof;

R^{17} is hydrogen, C_1 to C_4 alkyl or C_2 to C_4 alkenyl;

R^{15} is optionally interrupted by oxygen, nitrogen, sulfur or any combination thereof; and

R^{16} is hydrogen, C_1 to C_4 alkyl or C_2 to C_4 alkenyl;

and n is from 1 to 5, or salt thereof.

Claim 24 (Previously Presented): A method as defined in claim 23, wherein said biologically active agent is selected from the group consisting of a peptide, a micropolysaccharide, a carbohydrate, a lipid, a pesticide, or any combination of the foregoing.

Claim 25 (Previously Presented): A method as defined in claim 24, wherein said biologically-active agent is selected from the group consisting of human growth hormone, bovine growth hormone, growth hormone-releasing hormone, an interferon, interleukin-II, insulin, heparin, calcitonin, erythropoietin, atrial naturetic factor, an antigen, a monoclonal antibody, somatostatin, adrenocorticotropin, gonadotropin releasing hormone, oxytocin, vasopressin, cromolyn sodium, vancomycin, desferrioxamine (DFO), low molecular weight heparin, antimicrobials, or any combination of any of the foregoing.

Claim 26 (Previously Presented): A method as defined in claim 23, wherein said perturbant comprises a proteinoid.

Claims 27 - 30 (Canceled)

Claim 31 (Currently amended): A method as defined in claim 23, wherein said perturbant comprises a carboxylic acid having the formula

$$R—CO_2H$$

wherein R is C_1 to C_{24} alkyl, C_2 to C_{24} alkenyl, C_3 to C_{10} cycloalkyl, C_3 to C_{10} cycloalkenyl, phenyl, naphthyl, (C_1 to C_{10} alkyl)phenyl, (C_2 to C_{10} alkenyl)phenyl, (C_1 to C_{10} alkyl)naphthyl, (C_2 to C_{10} alkenyl)naphthyl, phenyl(C_1 to C_{10} alkyl), phenyl(C_2 to C_{10} alkenyl), naphthyl(C_1 to C_{10} alkyl) and naphthyl(C_2 to C_{10} alkenyl);

R being optionally substituted with C_1 to C_{10} alkyl, C_2 to C_{10} alkenyl, C_1 to C_4 alkoxy, -OH, -SH, $-CO_2R^1$, C_3 to C_{10} cycloalkyl, C_3 to C_{10} cycloalkenyl, ~~heterocyclic having 3-10 ring atoms~~

~~wherein the hetero atom is one or more atoms of N, O, S or any combination thereof,~~ aryl, (C_1 to C_{10} alkyl)aryl, aryl(C_1 to C_{10})alkyl, or any combination thereof;

R being optionally interrupted by oxygen, nitrogen, sulfur, or any combination thereof; and

R^1 is hydrogen, C_1 to C_4 alkyl or C_2 to C_4 alkenyl; or

a salt thereof.

Claim 32 (Previously Presented): The method of claim 23, wherein said biologically active agent is introduced to

(a) an excipient,

(b) a diluent,

(c) a disintegrant,

(d) a lubricant,

(e) a plasticizer,

(f) a colorant,

(g) a dosing vehicle, or

(h) any combination thereof.

Claim 33 (Currently Amended): A method for subcutaneously administering an active agent said method comprising:

(a) providing a biologically active agent which can exist in a native conformational state, a denatured conformational state, and an intermediate conformational state which is reversible to said native state and is conformationally between said native and denatured states;

(b) exposing said biologically active agent to a complexing perturbant to reversibly transform said biologically active agent to said intermediate state and to form a subcutaneously administrable supramolecular complex,

said perturbant having a molecular weight between about 150 and about 600 daltons, and having at least one hydrophilic moiety and one hydrophilic moiety,

said supramolecular complex comprising said perturbant non-covalently complexed with said biologically active agent, and

said biologically active agent not forming a microsphere with said perturbant;

wherein said perturbant is in an amount effective for subcutaneous delivery of said biologically active agent; and

(c) preparing a mimetic of said supramolecular complex, and

(d) subcutaneously administering said mimetic, wherein said perturbant is selected is selected from the group consisting of (a) a carboxylic acid having the formula

$$R—CO_2H$$

wherein R is C_1 to C_{24} alkyl, C_2 to C_{24} alkenyl, C_3 to C_{10} cycloalkyl, C_3 to C_{10} cycloalkenyl, phenyl, naphthyl, (C_1 to C_{10} alkyl)phenyl, (C_2 to C_{10} alkenyl)phenyl, (C_1 to C_{10} alkyl) naphthyl, (C_2 to C_{10} alkenyl)naphthyl, phenyl(C_1 to C_{10} alkyl), phenyl(C_2 to C_{10} alkenyl), naphthyl(C_1 to C_{10} alkyl) and naphthyl(C_2 to C_{10} alkenyl);

R being optionally substituted with C_1 to C_{10} alkyl, C_2 to C_{10} alkenyl, C_1 to C_4 alkoxy, -OH, -SH, $-CO_2R^1$, C_3 to C_{10} cycloalkyl, C_3 to C_{10} cycloalkenyl, aryl, (C_1 to C_{10} alkyl)aryl, aryl(C_1 to C_{10})alkyl, or any combination thereof;

R being optionally interrupted by oxygen, nitrogen, sulfur, or any combination thereof; and

R^1 is hydrogen, C_1 to C_4 alkyl or C_2 to C_4 alkenyl; or

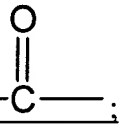
a salt thereof, and

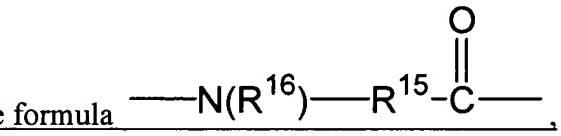
(b) an acylated amino acid having the formula having the formula:

$$Ar\text{-}Y\text{-}(R^{14})_n\text{-}OH$$

wherein:

Ar is a substituted or unsubstituted phenyl or naphthyl;

Y is  ;

R^{14} has the formula  ,

R^{15} is C_1 to C_{24} alkyl, C_2 to C_{24} alkenyl, phenyl, naphthyl, (C_1 to C_{10} alkyl) phenyl, (C_2 to C_{10} alkenyl) phenyl, (C_1 to C_{10} alkyl) naphthyl, (C_2 to C_{10} alkenyl) naphthyl, phenyl (C_1 to C_{10} alkyl), phenyl (C_2 to C_{10} alkenyl), naphthyl (C_1 to C_{10} alkyl), and naphthyl (C_2 to C_{10} alkenyl);

R^{15} is optionally substituted with C_1 to C_4 alkyl, C_1 to C_4 alkenyl, C_1 to C_4 alkoxy, -OH, -SH, $-CO_2R^{17}$, cycloalkyl, cycloalkenyl, heterocyclic alkyl, alkaryl, heteroaryl, heteroalkaryl, or any combination thereof;

R^{17} is hydrogen, C_1 to C_4 alkyl or C_2 to C_4 alkenyl;

R^{15} is optionally interrupted by oxygen, nitrogen, sulfur or any combination thereof; and

R^{16} is hydrogen, C_1 to C_4 alkyl or C_2 to C_4 alkenyl;

and n is from 1 to 5, or salt thereof.

Claim 34 (Original): A method as defined in claim 33, wherein said biologically active agent comprises a peptide and said mimetic comprises a peptide mimetic.

Claim 35 (Currently Amended): A method for subcutaneously administering a biologically active agent, said method comprising:

(a) providing a biologically active agent which can exist in a native conformational state, a denatured conformational state, and an intermediate which is reversible to said native state and is conformationally between said native and denatured states;

(b) exposing said biologically active agent to a perturbant to reversibly transform said biologically active agent to said intermediate state, wherein said perturbant is in an amount effective for subcutaneous delivery of said biologically active agent; and

(c) preparing a mimetic of said intermediate state, and

(d) subcutaneously administering said mimetic, wherein said perturbant is selected from the group consisting of (a) a carboxylic acid having the formula

$$R—CO_2H$$

wherein R is C_1 to C_{24} alkyl, C_2 to C_{24} alkenyl, C_3 to C_{10} cycloalkyl, C_3 to C_{10} cycloalkenyl, phenyl, naphthyl, (C_1 to C_{10} alkyl)phenyl, (C_2 to C_{10} alkenyl)phenyl, (C_1 to C_{10} alkyl) naphthyl, (C_2 to C_{10} alkenyl)naphthyl, phenyl(C_1 to C_{10} alkyl), phenyl(C_2 to C_{10} alkenyl), naphthyl(C_1 to C_{10} alkyl) and naphthyl(C_2 to C_{10} alkenyl);

R being optionally substituted with C_1 to C_{10} alkyl, C_2 to C_{10} alkenyl, C_1 to C_4 alkoxy, -OH, -SH, $-CO_2R^1$, C_3 to C_{10} cycloalkyl, C_3 to C_{10} cycloalkenyl, aryl, (C_1 to C_{10} alkyl)aryl, aryl(C_1 to C_{10})alkyl, or any combination thereof;

R being optionally interrupted by oxygen, nitrogen, sulfur, or any combination thereof; and

R^1 is hydrogen, C_1 to C_4 alkyl or C_2 to C_4 alkenyl; or

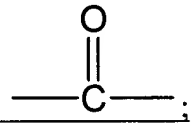
a salt thereof, and

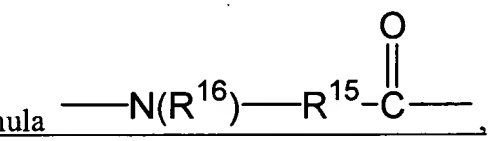
(b) an acylated amino acid having the formula having the formula:

$$Ar\text{-}Y\text{-}(R^{14})_n\text{-}OH$$

wherein:

Ar is a substituted or unsubstituted phenyl or naphthyl;

Y is  ;

R^{14} has the formula  ,

R^{15} is C_1 to C_{24} alkyl, C_2 to C_{24} alkenyl, phenyl, naphthyl, (C_1 to C_{10} alkyl) phenyl, (C_2 to C_{10} alkenyl) phenyl, (C_1 to C_{10} alkyl) naphthyl, (C_2 to C_{10} alkenyl) naphthyl, phenyl (C_1 to C_{10} alkyl), phenyl (C_2 to C_{10} alkenyl), naphthyl (C_1 to C_{10} alkyl), and naphthyl (C_2 to C_{10} alkenyl);

R^{15} is optionally substituted with C_1 to C_4 alkyl, C_1 to C_4 alkenyl, C_1 to C_4 alkoxy, -OH, -SH, $-CO_2R^{17}$, cycloalkyl, cycloalkenyl, heterocyclic alkyl, alkaryl, heteroaryl, heteroalkaryl, or any combination thereof;

R^{17} is hydrogen, C_1 to C_4 alkyl or C_2 to C_4 alkenyl;

R^{15} is optionally interrupted by oxygen, nitrogen, sulfur or any combination thereof; and

R^{16} is hydrogen, C_1 to C_4 alkyl or C_2 to C_4 alkenyl;

and n is from 1 to 5, or salt thereof.

Claim 36 (Currently Amended): A method as defined in claim 35, wherein said perturbant further comprises a pH changing agent, an ionic strength changing agent, or guanidine hydrochloride.

Claims 37-49 (Canceled)

Claim 50 (Currently Amended): A method for sublingually administering a biologically active agent, said method comprising:

(a) providing a biologically active agent which can exist in a native conformational state, a denatured conformational state, and an intermediate conformational state which is reversible to said native state and is conformationally between said native and denatured states; and

(b) exposing said biologically active agent to a complexing perturbant to reversibly transform said biologically active agent to said intermediate state and to form a sublingually administrable supramolecular complex, and

(c) sublingually administering said supramolecular complex

said perturbant having a molecular weight ranging from about 150 to about 600 daltons, and having at least one hydrophilic moiety and at least one hydrophobic moiety,

said supramolecular complex comprising said perturbant non-covalently complexed with said biologically active agent; and

said biologically active agent not forming a microsphere with said perturbant;

wherein said perturbant is in an amount effective for sublingual delivery of said biologically active agent;

wherein said perturbant is selected from the group consisting of (a) a carboxylic acid having the formula

$$R—CO_2H$$

wherein R is C_1 to C_{24} alkyl, C_2 to C_{24} alkenyl, C_3 to C_{10} cycloalkyl, C_3 to C_{10} cycloalkenyl, phenyl, naphthyl, (C_1 to C_{10} alkyl)phenyl, (C_2 to C_{10} alkenyl)phenyl, (C_1 to C_{10} alkyl) naphthyl, (C_2 to C_{10} alkenyl)naphthyl, phenyl(C_1 to C_{10} alkyl), phenyl(C_2 to C_{10} alkenyl), naphthyl(C_1 to C_{10} alkyl) and naphthyl(C_2 to C_{10} alkenyl);

R being optionally substituted with C_1 to C_{10} alkyl, C_2 to C_{10} alkenyl, C_1 to C_4 alkoxy, -OH, -SH, $-CO_2R^1$, C_3 to C_{10} cycloalkyl, C_3 to C_{10} cycloalkenyl, aryl, (C_1 to C_{10} alkyl)aryl, aryl(C_1 to C_{10})alkyl, or any combination thereof;

R being optionally interrupted by oxygen, nitrogen, sulfur, or any combination thereof; and

R^1 is hydrogen, C_1 to C_4 alkyl or C_2 to C_4 alkenyl; or

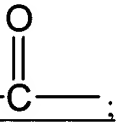
a salt thereof, and

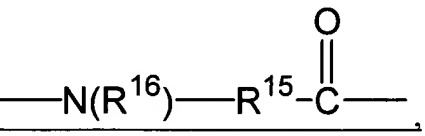
(b) an acylated amino acid having the formula having the formula:

$$Ar\text{-}Y\text{-}(R^{14})_n\text{-}OH$$

wherein:

Ar is a substituted or unsubstituted phenyl or naphthyl;

Y is  ;

R^{14} has the formula  ,

R^{15} is C_1 to C_{24} alkyl, C_2 to C_{24} alkenyl, phenyl, naphthyl, (C_1 to C_{10} alkyl) phenyl, (C_2 to C_{10} alkenyl) phenyl, (C_1 to C_{10} alkyl) naphthyl, (C_2 to C_{10} alkenyl) naphthyl, phenyl (C_1 to C_{10} alkyl), phenyl (C_2 to C_{10} alkenyl), naphthyl (C_1 to C_{10} alkyl), and naphthyl (C_2 to C_{10} alkenyl);

R^{15} is optionally substituted with C_1 to C_4 alkyl, C_1 to C_4 alkenyl, C_1 to C_4 alkoxy, -OH, -SH, $-CO_2R^{17}$, cycloalkyl, cycloalkenyl, heterocyclic alkyl, alkaryl, heteroaryl, heteroalkaryl, or any combination thereof;

R^{17} is hydrogen, C_1 to C_4 alkyl or C_2 to C_4 alkenyl;

R^{15} is optionally interrupted by oxygen, nitrogen, sulfur or any combination thereof; and

R^{16} is hydrogen, C_1 to C_4 alkyl or C_2 to C_4 alkenyl;

and n is from 1 to 5, or salt thereof.

Claim 51 (Original): A method as defined in claim 50, wherein said intermediate state has ΔG ranging from about -20 kcal/mole to about 20 kcal/moles relative to said native state.

Claim 52 (Original): A method as defined in claim 50, wherein said biologically active agent is selected from the group consisting of a peptide, a micropolysaccharide, a carbohydrate, a lipid, a pesticide, or any combination of the foregoing.

Claim 53 (Previously Presented): A method as defined in claim 52, wherein said biologically-active agent is selected from the group consisting of human growth hormone, bovine growth hormone, growth hormone-releasing hormone, an interferon, interleukin-II, insulin, heparin, calcitonin, erythropoietin, atrial naturetic factor, an antigen, a monoclonal antibody, somatostatin,

adrenocorticotropin, gonadotropin releasing hormone, oxytocin, vasopressin, cromolyn sodium, vancomycin, desferrioxamine (DFO), low molecular weight heparin, antimicrobials, or any combination of any of the foregoing.

Claims 54 -58 (Canceled).

Claim 59 (Currently amended): A method as defined in claim 50, wherein said perturbant comprises a carboxylic acid having the formula

$$R—CO_2H$$

wherein R is C_1 to C_{24} alkyl, C_2 to C_{24} alkenyl, C_3 to C_{10} cycloalkyl, C_3 to C_{10} cycloalkenyl, phenyl, naphthyl, (C_1 to C_{10} alkyl)phenyl, (C_2 to C_{10} alkenyl)phenyl, (C_1 to C_{10} alkyl)naphthyl, (C_2 to C_{10} alkenyl)naphthyl, phenyl(C_1 to C_{10} alkyl), phenyl(C_2 to C_{10} alkenyl), naphthyl(C_1 to C_{10} alkyl) and naphthyl(C_2 to C_{10} alkenyl);

R being optionally substituted with C_1 to C_{10} alkyl, C_2 to C_{10} alkenyl, C_1 to C_4 alkoxy, -OH, -SH, $-CO_2R^1$, C_3 to C_{10} cycloalkyl, C_3 to C_{10} cycloalkenyl, ~~heterocyclic having 3-10 ring atoms wherein the hetero atom is one or more atoms of N, O, S or any combination thereof,~~ aryl, (C_1 to C_{10} alkyl)aryl, aryl(C_1 to C_{10})alkyl, or any combination thereof;

R being optionally interrupted by oxygen, nitrogen, sulfur, or any combination thereof; and

R^1 is hydrogen, C_1 to C_4 alkyl or C_2 to C_4 alkenyl; or

a salt thereof.

Claim 60 (Currently amended): A method for sublingually administering a biologically active agent comprising:

(a) providing a biologically active agent in an intermediate conformational state non-covalently complexed with a complexing perturbant having a molecular weight ranging from about 150 to about 600 and having at least one hydrophilic moiety and at least one hydrophobic moiety;

(b) sublingually administering said biologically active agent

wherein said intermediate state is reversible to said native state and is conformationally between a native conformational and a denatured conformational state of said biologically active agent and said composition is not a microsphere; and wherein said perturbant is in an amount effective for sublingual delivery of said biologically active agent;

wherein said perturbant is selected from the group consisting of (a) a carboxylic acid having the formula

$$R—CO_2H$$

wherein R is C_1 to C_{24} alkyl, C_2 to C_{24} alkenyl, C_3 to C_{10} cycloalkyl, C_3 to C_{10} cycloalkenyl, phenyl, naphthyl, (C_1 to C_{10} alkyl)phenyl, (C_2 to C_{10} alkenyl)phenyl, (C_1 to C_{10} alkyl) naphthyl, (C_2 to C_{10} alkenyl)naphthyl, phenyl(C_1 to C_{10} alkyl), phenyl(C_2 to C_{10} alkenyl), naphthyl(C_1 to C_{10} alkyl) and naphthyl(C_2 to C_{10} alkenyl);

R being optionally substituted with C_1 to C_{10} alkyl, C_2 to C_{10} alkenyl, C_1 to C_4 alkoxy, -OH, -SH, $-CO_2R^1$, C_3 to C_{10} cycloalkyl, C_3 to C_{10} cycloalkenyl, aryl, (C_1 to C_{10} alkyl)aryl, aryl(C_1 to C_{10})alkyl, or any combination thereof;

R being optionally interrupted by oxygen, nitrogen, sulfur, or any combination thereof; and

R^1 is hydrogen, C_1 to C_4 alkyl or C_2 to C_4 alkenyl; or

a salt thereof, and

(b) an acylated amino acid having the formula having the formula:

$$Ar\text{-}Y\text{-}(R^{14})_n\text{-}OH$$

wherein:

Ar is a substituted or unsubstituted phenyl or naphthyl;

Y is  ;

R^{14} has the formula  ,

R^{15} is C_1 to C_{24} alkyl, C_2 to C_{24} alkenyl, phenyl, naphthyl, (C_1 to C_{10} alkyl) phenyl, (C_2 to C_{10} alkenyl) phenyl, (C_1 to C_{10} alkyl) naphthyl, (C_2 to C_{10} alkenyl) naphthyl, phenyl (C_1 to C_{10} alkyl), phenyl (C_2 to C_{10} alkenyl), naphthyl (C_1 to C_{10} alkyl), and naphthyl (C_2 to C_{10} alkenyl);

R^{15} is optionally substituted with C_1 to C_4 alkyl, C_1 to C_4 alkenyl, C_1 to C_4 alkoxy, -OH, -SH, $-CO_2R^{17}$, cycloalkyl, cycloalkenyl, heterocyclic alkyl, alkaryl, heteroaryl, heteroalkaryl, or any combination thereof;

R^{17} is hydrogen, C_1 to C_4 alkyl or C_2 to C_4 alkenyl;

R^{15} is optionally interrupted by oxygen, nitrogen, sulfur or any combination thereof; and

R^{16} is hydrogen, C_1 to C_4 alkyl or C_2 to C_4 alkenyl;

and n is from 1 to 5, or salt thereof.

Claim 61 (Previously Presented): A method as defined in claim 60, wherein said biologically active agent is selected from the group consisting of a peptide, a micropolysaccharide, a carbohydrate, a lipid, a pesticide, or any combination of the foregoing.

Claim 62 (Previously Presented): A method as defined in claim 61, wherein said biologically-active agent is selected from the group consisting of human growth hormone, bovine growth hormone, growth hormone-releasing hormone, an interferon, interleukin-II, insulin, heparin, calcitonin, erythropoietin, atrial naturetic factor, an antigen, a monoclonal antibody, somatostatin, adrenocorticotropin, gonadotropin releasing hormone, oxytocin, vasopressin, cromolyn sodium, vancomycin, desferrioxamine (DFO), low molecular weight heparin, anitmicrobials, or any combination of any of the foregoing.

Claims 63 - 67 (Canceled).

Claim 68 (Currently amended): A method as defined in claim 60, wherein said perturbant comprises a carboxylic acid having the formula

$$R—CO_2H$$

wherein R is C_1 to C_{24} alkyl, C_2 to C_{24} alkenyl, C_3 to C_{10} cycloalkyl, C_3 to C_{10} cycloalkenyl, phenyl, naphthyl, (C_1 to C_{10} alkyl)phenyl, (C_2 to C_{10} alkenyl)phenyl, (C_1 to C_{10} alkyl)naphthyl, (C_2 to C_{10} alkenyl)naphthyl, phenyl(C_1 to C_{10} alkyl), phenyl(C_2 to C_{10} alkenyl), naphthyl(C_1 to C_{10} alkyl) and naphthyl(C_2 to C_{10} alkenyl);

R being optionally substituted with C_1 to C_{10} alkyl, C_2 to C_{10} alkenyl, C_1 to C_4 alkoxy, -OH,

-SH, $-CO_2R^1$, C_3 to C_{10} cycloalkyl, C_3 to C_{10} cycloalkenyl, ~~heterocyclic having 3-10 ring atoms wherein the hetero atom is one or more atoms of N, O, S or any combination thereof,~~ aryl, (C_1 to C_{10} alkyl)aryl, aryl(C_1 to C_{10})alkyl, or any combination thereof;

R being optionally interrupted by oxygen, nitrogen, sulfur, or any combination thereof; and

R^1 is hydrogen, C_1 to C_4 alkyl or C_2 to C_4 alkenyl; or

a salt thereof.

Claim 69 (Previously Presented): A method as defined in claim 60, wherein said biologically active agent is introduced to:

(a) an excipient,

(b) a diluent,

(c) a disintegrant,

(d) a lubricant,

(e) a plasticizer,

(f) a colorant,

(g) a dosing vehicle, or

(h) any combination thereof.

Claim 70 (Currently Amended): A method for sublingually administering an agent to a subject in need of said agent, said method comprising:

(a) providing a biologically active agent which can exist in a native conformational state, a denatured conformational state, and an intermediate conformational state which is reversible to

said native state and is conformationally between said native and denatured states;

(b) exposing said biologically active agent to a complexing perturbant to reversibly transform said biologically active agent to said intermediate state and to form a sublingually administrable supramolecular complex,

said perturbant having a molecular weight between about 150 and about 600 daltons, and having at least one hydrophilic moiety and one hydrophilic moiety,

said supramolecular complex comprising said perturbant non-covalently complexed with said biologically active agent, and

said biologically active agent not forming a microsphere with said perturbant;

wherein said perturbant is in an amount effective for sublingual delivery of said biologically active agent; and

(c) preparing a mimetic of said supramolecular complex, and

(d) sublingually administering said mimetic, wherein said perturbant is selected from the group consisting of (a) a carboxylic acid having the formula

$$R—CO_2H$$

wherein R is C_1 to C_{24} alkyl, C_2 to C_{24} alkenyl, C_3 to C_{10} cycloalkyl, C_3 to C_{10} cycloalkenyl, phenyl, naphthyl, (C_1 to C_{10} alkyl)phenyl, (C_2 to C_{10} alkenyl)phenyl, (C_1 to C_{10} alkyl) naphthyl, (C_2 to C_{10} alkenyl)naphthyl, phenyl(C_1 to C_{10} alkyl), phenyl(C_2 to C_{10} alkenyl), naphthyl(C_1 to C_{10} alkyl) and naphthyl(C_2 to C_{10} alkenyl);

R being optionally substituted with C_1 to C_{10} alkyl, C_2 to C_{10} alkenyl, C_1 to C_4 alkoxy, -OH, -SH, $-CO_2R^1$, C_3 to C_{10} cycloalkyl, C_3 to C_{10} cycloalkenyl, aryl, (C_1 to C_{10} alkyl)aryl, aryl(C_1 to C_{10})alkyl, or any combination thereof;

R being optionally interrupted by oxygen, nitrogen, sulfur, or any combination thereof; and

R^1 is hydrogen, C_1 to C_4 alkyl or C_2 to C_4 alkenyl; or

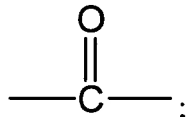
a salt thereof, and

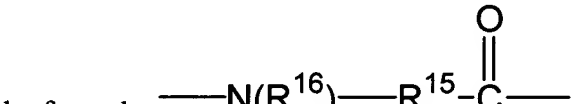
(b) an acylated amino acid having the formula having the formula:

$$Ar\text{-}Y\text{-}(R^{14})_n\text{-}OH$$

wherein:

Ar is a substituted or unsubstituted phenyl or naphthyl;

Y is  ;

R^{14} has the formula  ,

R^{15} is C_1 to C_{24} alkyl, C_2 to C_{24} alkenyl, phenyl, naphthyl, (C_1 to C_{10} alkyl) phenyl, (C_2 to C_{10} alkenyl) phenyl, (C_1 to C_{10} alkyl) naphthyl, (C_2 to C_{10} alkenyl) naphthyl, phenyl (C_1 to C_{10} alkyl), phenyl (C_2 to C_{10} alkenyl), naphthyl (C_1 to C_{10} alkyl), and naphthyl (C_2 to C_{10} alkenyl);

R^{15} is optionally substituted with C_1 to C_4 alkyl, C_1 to C_4 alkenyl, C_1 to C_4 alkoxy, -OH, -SH, $-CO_2R^{17}$, cycloalkyl, cycloalkenyl, heterocyclic alkyl, alkaryl, heteroaryl, heteroalkaryl, or any combination thereof;

R^{17} is hydrogen, C_1 to C_4 alkyl or C_2 to C_4 alkenyl;

R^{15} is optionally interrupted by oxygen, nitrogen, sulfur or any combination thereof; and

R^{16} is hydrogen, C_1 to C_4 alkyl or C_2 to C_4 alkenyl;

and n is from 1 to 5, or salt thereof.

Claim 71 (Original): A method as defined in claim 70, wherein said biologically active agent comprises a peptide and said mimetic comprises a peptide mimetic.

Claim 72 (Currently Amended): A method for sublingually administering a biologically active agent to a subject in need of said agent, said method comprising:

(a) providing a biologically active agent which can exist in a native conformational state, a denatured conformational state, and an intermediate which is reversible to said native state and is conformationally between said native and denatured states;

(b) exposing said biologically active agent to a perturbant to reversibly transform said biologically active agent to said intermediate state, wherein said perturbant is in an amount effective for sublingual delivery of said biologically active agent; and

(c) preparing a mimetic of said intermediate state, and

(d) sublingually administering said mimetic, wherein said perturbant is selected from the group consisting of (a) a carboxylic acid having the formula

$$R—CO_2H$$

wherein R is C_1 to C_{24} alkyl, C_2 to C_{24} alkenyl, C_3 to C_{10} cycloalkyl, C_3 to C_{10} cycloalkenyl, phenyl, naphthyl, (C_1 to C_{10} alkyl)phenyl, (C_2 to C_{10} alkenyl)phenyl, (C_1 to C_{10} alkyl) naphthyl, (C_2 to C_{10} alkenyl)naphthyl, phenyl(C_1 to C_{10} alkyl), phenyl(C_2 to C_{10} alkenyl), naphthyl(C_1 to C_{10} alkyl) and naphthyl(C_2 to C_{10} alkenyl);

R being optionally substituted with C_1 to C_{10} alkyl, C_2 to C_{10} alkenyl, C_1 to C_4 alkoxy, -OH, -SH, $-CO_2R^1$, C_3 to C_{10} cycloalkyl, C_3 to C_{10} cycloalkenyl, aryl, (C_1 to C_{10} alkyl)aryl, aryl(C_1 to C_{10})alkyl, or any combination thereof;

R being optionally interrupted by oxygen, nitrogen, sulfur, or any combination thereof; and

R^1 is hydrogen, C_1 to C_4 alkyl or C_2 to C_4 alkenyl; or

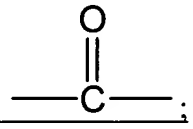
a salt thereof, and

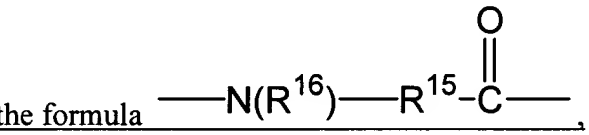
(b) an acylated amino acid having the formula having the formula:

$$Ar\text{-}Y\text{-}(R^{14})_n\text{-}OH$$

wherein:

Ar is a substituted or unsubstituted phenyl or naphthyl;

Y is  ;

R^{14} has the formula  ,

R^{15} is C_1 to C_{24} alkyl, C_2 to C_{24} alkenyl, phenyl, naphthyl, (C_1 to C_{10} alkyl) phenyl, (C_2 to C_{10} alkenyl) phenyl, (C_1 to C_{10} alkyl) naphthyl, (C_2 to C_{10} alkenyl) naphthyl, phenyl (C_1 to C_{10} alkyl), phenyl (C_2 to C_{10} alkenyl), naphthyl (C_1 to C_{10} alkyl), and naphthyl (C_2 to C_{10} alkenyl);

R^{15} is optionally substituted with C_1 to C_4 alkyl, C_1 to C_4 alkenyl, C_1 to C_4 alkoxy, -OH, -SH, $-CO_2R^{17}$, cycloalkyl, cycloalkenyl, heterocyclic alkyl, alkaryl, heteroaryl, heteroalkaryl, or any combination thereof;

R^{17} is hydrogen, C_1 to C_4 alkyl or C_2 to C_4 alkenyl;

R^{15} is optionally interrupted by oxygen, nitrogen, sulfur or any combination thereof; and

R^{16} is hydrogen, C_1 to C_4 alkyl or C_2 to C_4 alkenyl;

and n is from 1 to 5, or salt thereof.

Claim 73 (Original): A method as defined in claim 72, wherein said perturbant further comprises a pH changing agent, an ionic strength changing agent, or guanidine hydrochloride.

Claims 74-86 (Canceled)

Claim 87 (Currently Amended): A method for intranasally administering a biologically active agent, said method comprising:

(a) providing a biologically active agent which can exist in a native conformational state, a denatured conformational state, and an intermediate conformational state which is reversible to said native state and is conformationally between said native and denatured states; and

(b) exposing said biologically active agent to a complexing perturbant to reversibly transform said biologically active agent to said intermediate state and to form an intranasally administrable supramolecular complex, and

(c) intranasally administering said supramolecular complex,

said perturbant having a molecular weight ranging from about 150 to about 600 daltons, and having at least one hydrophilic moiety and at least one hydrophobic moiety,

said supramolecular complex comprising said perturbant non-covalently complexed with said biologically active agent; and

said biologically active agent not forming a microsphere with said perturbant;

wherein said perturbant is in an amount effective for intranasal delivery of said biologically active agent;

wherein said perturbant is selected from the group consisting of (a) a carboxylic acid having the formula

$$R—CO_2H$$

wherein R is C_1 to C_{24} alkyl, C_2 to C_{24} alkenyl, C_3 to C_{10} cycloalkyl, C_3 to C_{10} cycloalkenyl, phenyl, naphthyl, (C_1 to C_{10} alkyl)phenyl, (C_2 to C_{10} alkenyl)phenyl, (C_1 to C_{10} alkyl) naphthyl, (C_2 to C_{10} alkenyl)naphthyl, phenyl(C_1 to C_{10} alkyl), phenyl(C_2 to C_{10} alkenyl), naphthyl(C_1 to C_{10} alkyl) and naphthyl(C_2 to C_{10} alkenyl);

R being optionally substituted with C_1 to C_{10} alkyl, C_2 to C_{10} alkenyl, C_1 to C_4 alkoxy, -OH, -SH, $-CO_2R^1$, C_3 to C_{10} cycloalkyl, C_3 to C_{10} cycloalkenyl, aryl, (C_1 to C_{10} alkyl)aryl, aryl(C_1 to C_{10})alkyl, or any combination thereof;

R being optionally interrupted by oxygen, nitrogen, sulfur, or any combination thereof; and

R^1 is hydrogen, C_1 to C_4 alkyl or C_2 to C_4 alkenyl; or

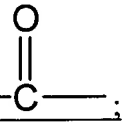
a salt thereof, and

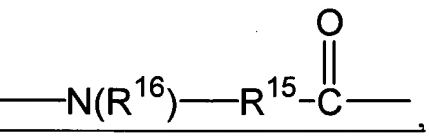
(b) an acylated amino acid having the formula having the formula:

$$Ar\text{-}Y\text{-}(R^{14})_n\text{-}OH$$

wherein:

Ar is a substituted or unsubstituted phenyl or naphthyl;

Y is  ;

R^{14} has the formula  ,

R^{15} is C_1 to C_{24} alkyl, C_2 to C_{24} alkenyl, phenyl, naphthyl, (C_1 to C_{10} alkyl) phenyl, (C_2 to C_{10} alkenyl) phenyl, (C_1 to C_{10} alkyl) naphthyl, (C_2 to C_{10} alkenyl) naphthyl, phenyl (C_1 to C_{10} alkyl), phenyl (C_2 to C_{10} alkenyl), naphthyl (C_1 to C_{10} alkyl), and naphthyl (C_2 to C_{10} alkenyl);

R^{15} is optionally substituted with C_1 to C_4 alkyl, C_1 to C_4 alkenyl, C_1 to C_4 alkoxy, -OH, -SH, $-CO_2R^{17}$, cycloalkyl, cycloalkenyl, heterocyclic alkyl, alkaryl, heteroaryl, heteroalkaryl, or any combination thereof;

R^{17} is hydrogen, C_1 to C_4 alkyl or C_2 to C_4 alkenyl;

R^{15} is optionally interrupted by oxygen, nitrogen, sulfur or any combination thereof; and

R^{16} is hydrogen, C_1 to C_4 alkyl or C_2 to C_4 alkenyl;

and n is from 1 to 5, or salt thereof.

Claim 88 (Original): A method as defined in claim 87, wherein said intermediate state has ΔG ranging from about -20 kcal/mole to about 20 kcal/moles relative to said native state.

Claim 89 (Original): A method as defined in claim 87, wherein said biologically active agent is selected from the group consisting of a peptide, a micropolysaccharide, a carbohydrate, a lipid, a pesticide, or any combination of the foregoing.

Claim 90 (Previously Presented): A method as defined in claim 89, wherein said biologically-active agent is selected from the group consisting of human growth hormone, bovine growth hormone, growth hormone-releasing hormone, an interferon, interleukin-II, insulin, heparin, calcitonin, erythropoietin, atrial naturetic factor, an antigen, a monoclonal antibody, somatostatin,

adrenocorticotropin, gonadotropin releasing hormone, oxytocin, vasopressin, cromolyn sodium, vancomycin, desferrioxamine (DFO), low molecular weight heparin, antimicrobials, or any combination of any of the foregoing.

Claims 91-95 (Canceled).

Claim 96 (Currently amended): A method as defined in claim 87, wherein said perturbant comprises a carboxylic acid having the formula

$$R—CO_2H$$

wherein R is C_1 to C_{24} alkyl, C_2 to C_{24} alkenyl, C_3 to C_{10} cycloalkyl, C_3 to C_{10} cycloalkenyl, phenyl, naphthyl, (C_1 to C_{10} alkyl)phenyl, (C_2 to C_{10} alkenyl)phenyl, (C_1 to C_{10} alkyl)naphthyl, (C_2 to C_{10} alkenyl)naphthyl, phenyl(C_1 to C_{10} alkyl), phenyl(C_2 to C_{10} alkenyl), naphthyl(C_1 to C_{10} alkyl) and naphthyl(C_2 to C_{10} alkenyl);

R being optionally substituted with C_1 to C_{10} alkyl, C_2 to C_{10} alkenyl, C_1 to C_4 alkoxy, -OH, -SH, $-CO_2R^1$, C_3 to C_{10} cycloalkyl, C_3 to C_{10} cycloalkenyl, ~~heterocyclic having 3-10 ring atoms wherein the hetero atom is one or more atoms of N, O, S or any combination thereof,~~ aryl, (C_1 to C_{10} alkyl)aryl, aryl(C_1 to C_{10})alkyl, or any combination thereof;

R being optionally interrupted by oxygen, nitrogen, sulfur, or any combination thereof; and

R^1 is hydrogen, C_1 to C_4 alkyl or C_2 to C_4 alkenyl; or

a salt thereof.

Claim 97 (Currently amended): A method for intranasally administering a biologically active agent comprising:

(a) providing a biologically active agent in an intermediate conformational state non-covalently complexed with a complexing perturbant having a molecular weight ranging from about 150 to about 600 and having at least one hydrophilic moiety and at least one hydrophobic moiety; and

(b) intranasally administering said biologially active agent

wherein said intermediate state is reversible to said native state and is conformationally between a native conformational and a denatured conformational state of said biologically active agent and said composition is not a microsphere; and wherein said perturbant is in an amount effective for intranasal delivery of said biologically active agent;

wherein said perturbant is selected from the group consisting of (a) a carboxylic acid having the formula

$$R—CO_2H$$

wherein R is C_1 to C_{24} alkyl, C_2 to C_{24} alkenyl, C_3 to C_{10} cycloalkyl, C_3 to C_{10} cycloalkenyl, phenyl, naphthyl, (C_1 to C_{10} alkyl)phenyl, (C_2 to C_{10} alkenyl)phenyl, (C_1 to C_{10} alkyl) naphthyl, (C_2 to C_{10} alkenyl)naphthyl, phenyl(C_1 to C_{10} alkyl), phenyl(C_2 to C_{10} alkenyl), naphthyl(C_1 to C_{10} alkyl) and naphthyl(C_2 to C_{10} alkenyl);

R being optionally substituted with C_1 to C_{10} alkyl, C_2 to C_{10} alkenyl, C_1 to C_4 alkoxy, -OH, -SH, $-CO_2R^1$, C_3 to C_{10} cycloalkyl, C_3 to C_{10} cycloalkenyl, aryl, (C_1 to C_{10} alkyl)aryl, aryl(C_1 to C_{10})alkyl, or any combination thereof;

R being optionally interrupted by oxygen, nitrogen, sulfur, or any combination thereof; and

R^1 is hydrogen, C_1 to C_4 alkyl or C_2 to C_4 alkenyl; or

a salt thereof, and

(b) an acylated amino acid having the formula having the formula:

$$Ar\text{-}Y\text{-}(R^{14})_n\text{-}OH$$

wherein:

Ar is a substituted or unsubstituted phenyl or naphthyl;

Y is  ;

R^{14} has the formula  ,

R^{15} is C_1 to C_{24} alkyl, C_2 to C_{24} alkenyl, phenyl, naphthyl, (C_1 to C_{10} alkyl) phenyl, (C_2 to C_{10} alkenyl) phenyl, (C_1 to C_{10} alkyl) naphthyl, (C_2 to C_{10} alkenyl) naphthyl, phenyl (C_1 to C_{10} alkyl), phenyl (C_2 to C_{10} alkenyl), naphthyl (C_1 to C_{10} alkyl), and naphthyl (C_2 to C_{10} alkenyl);

R^{15} is optionally substituted with C_1 to C_4 alkyl, C_1 to C_4 alkenyl, C_1 to C_4 alkoxy, -OH, -SH, $-CO_2R^{17}$, cycloalkyl, cycloalkenyl, heterocyclic alkyl, alkaryl, heteroaryl, heteroalkaryl, or any combination thereof;

R^{17} is hydrogen, C_1 to C_4 alkyl or C_2 to C_4 alkenyl;

R^{15} is optionally interrupted by oxygen, nitrogen, sulfur or any combination thereof; and

R^{16} is hydrogen, C_1 to C_4 alkyl or C_2 to C_4 alkenyl;

and n is from 1 to 5, or salt thereof.

Claim 98 (Previously Presented): A method as defined in claim 97, wherein said biologically active agent is selected from the group consisting of a peptide, a micropolysaccharide, a carbohydrate, a lipid, a pesticide, or any combination of the foregoing.

Claim 99 (Previously Presented): A method as defined in claim 98, wherein said biologically-active agent is selected from the group consisting of human growth hormone, bovine growth hormone, growth hormone-releasing hormone, an interferon, interleukin-II, insulin, heparin, calcitonin, erythropoietin, atrial naturetic factor, an antigen, a monoclonal antibody, somatostatin, adrenocorticotropin, gonadotropin releasing hormone, oxytocin, vasopressin, cromolyn sodium, vancomycin, desferrioxamine (DFO), low molecular weight heparin, antimicrobials, or any combination of any of the foregoing.

Claims 100 - 104 (Canceled).

Claim 105 (Currently amended): A method as defined in claim 97, wherein said perturbant comprises a carboxylic acid having the formula

$$R—CO_2H$$

wherein R is C_1 to C_{24} alkyl, C_2 to C_{24} alkenyl, C_3 to C_{10} cycloalkyl, C_3 to C_{10} cycloalkenyl, phenyl, naphthyl, (C_1 to C_{10} alkyl)phenyl, (C_2 to C_{10} alkenyl)phenyl, (C_1 to C_{10} alkyl)naphthyl, (C_2 to C_{10} alkenyl)naphthyl, phenyl(C_1 to C_{10} alkyl), phenyl(C_2 to C_{10} alkenyl), naphthyl(C_1 to C_{10} alkyl) and naphthyl(C_2 to C_{10} alkenyl);

R being optionally substituted with C_1 to C_{10} alkyl, C_2 to C_{10} alkenyl, C_1 to C_4 alkoxy, -OH,

-SH, $-CO_2R^1$, C_3 to C_{10} cycloalkyl, C_3 to C_{10} cycloalkenyl, ~~heterocyclic having 3-10 ring atoms wherein the hetero atom is one or more atoms of N, O, S or any combination thereof,~~ aryl, (C_1 to C_{10} alkyl)aryl, aryl(C_1 to C_{10})alkyl, or any combination thereof;

R being optionally interrupted by oxygen, nitrogen, sulfur, or any combination thereof; and

R^1 is hydrogen, C_1 to C_4 alkyl or C_2 to C_4 alkenyl; or

a salt thereof.

Claim 106 (Previously Presented): A method as defined in claim 93, wherein said biologically active is introduced to:

(a) an excipient,

(b) a diluent,

(c) a disintegrant,

(d) a lubricant,

(e) a plasticizer,

(f) a colorant,

(g) a dosing vehicle, or

(h) any combination thereof.

Claim 107 (Currently Amended): A method for intranasally administering a biologically active agent to a subject in need of said agent, said method comprising:

(a) providing a biologically active agent which can exist in a native conformational state, a denatured conformational state, and an intermediate conformational state which is reversible to

said native state and is conformationally between said native and denatured states;

(b) exposing said biologically active agent to a complexing perturbant to reversibly transform said biologically active agent to said intermediate state and to form an intranasally administrable supramolecular complex,

said perturbant having a molecular weight between about 150 and about 600 daltons, and having at least one hydrophilic moiety and one hydrophilic moiety,

said supramolecular complex comprising said perturbant non-covalently complexed with said biologically active agent, and

said biologically active agent not forming a microsphere with said perturbant;

wherein said perturbant is in an amount effective for intranasal delivery of said biologically active agent; and

(c) preparing a mimetic of said supramolecular complex, and

(d) intranasally administering said supramolecular complex, wherein said perturbant is selected from the group consisting of (a) a carboxylic acid having the formula

$$R—CO_2H$$

wherein R is C_1 to C_{24} alkyl, C_2 to C_{24} alkenyl, C_3 to C_{10} cycloalkyl, C_3 to C_{10} cycloalkenyl, phenyl, naphthyl, (C_1 to C_{10} alkyl)phenyl, (C_2 to C_{10} alkenyl)phenyl, (C_1 to C_{10} alkyl) naphthyl, (C_2 to C_{10} alkenyl)naphthyl, phenyl(C_1 to C_{10} alkyl), phenyl(C_2 to C_{10} alkenyl), naphthyl(C_1 to C_{10} alkyl) and naphthyl(C_2 to C_{10} alkenyl);

R being optionally substituted with C_1 to C_{10} alkyl, C_2 to C_{10} alkenyl, C_1 to C_4 alkoxy, -OH, -SH, $-CO_2R^1$, C_3 to C_{10} cycloalkyl, C_3 to C_{10} cycloalkenyl, aryl, (C_1 to C_{10} alkyl)aryl, aryl(C_1 to C_{10})alkyl, or any combination thereof;

R being optionally interrupted by oxygen, nitrogen, sulfur, or any combination thereof; and

R^1 is hydrogen, C_1 to C_4 alkyl or C_2 to C_4 alkenyl; or

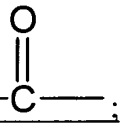
a salt thereof, and

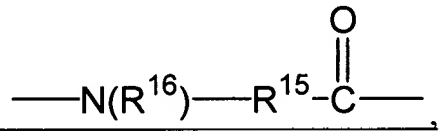
(b) an acylated amino acid having the formula having the formula:

$$Ar\text{-}Y\text{-}(R^{14})_n\text{-}OH$$

wherein:

Ar is a substituted or unsubstituted phenyl or naphthyl;

Y is  ;

R^{14} has the formula  ,

R^{15} is C_1 to C_{24} alkyl, C_2 to C_{24} alkenyl, phenyl, naphthyl, (C_1 to C_{10} alkyl) phenyl, (C_2 to C_{10} alkenyl) phenyl, (C_1 to C_{10} alkyl) naphthyl, (C_2 to C_{10} alkenyl) naphthyl, phenyl (C_1 to C_{10} alkyl), phenyl (C_2 to C_{10} alkenyl), naphthyl (C_1 to C_{10} alkyl), and naphthyl (C_2 to C_{10} alkenyl);

R^{15} is optionally substituted with C_1 to C_4 alkyl, C_1 to C_4 alkenyl, C_1 to C_4 alkoxy, -OH, -SH, $-CO_2R^{17}$, cycloalkyl, cycloalkenyl, heterocyclic alkyl, alkaryl, heteroaryl, heteroalkaryl, or any combination thereof;

R^{17} is hydrogen, C_1 to C_4 alkyl or C_2 to C_4 alkenyl;

R^{15} is optionally interrupted by oxygen, nitrogen, sulfur or any combination thereof; and

R^{16} is hydrogen, C_1 to C_4 alkyl or C_2 to C_4 alkenyl;

and n is from 1 to 5, or salt thereof.

Claim 108 (Original): A method as defined in claim 107, wherein said biologically active agent comprises a peptide and said mimetic comprises a peptide mimetic.

Claim 109 (Currently Amended): A method for intranasally administering a biollogically active agent to a subject in need of said agent, said method comprising:

(a) providing a biologically active agent which can exist in a native conformational state, a denatured conformational state, and an intermediate which is reversible to said native state and is conformationally between said native and denatured states;

(b) exposing said biologically active agent to a perturbant to reversibly transform said biologically active agent to said intermediate state, wherein said perturbant is in an amount effective for intranasal delivery of said biologically active agent; and

(c) preparing a mimetic of said intermediate state, and

(d) intranasally administering said biologically active agent, wherein said perturbant is selected from the group consisting of (a) a carboxylic acid having the formula

$$R—CO_2H$$

wherein R is C_1 to C_{24} alkyl, C_2 to C_{24} alkenyl, C_3 to C_{10} cycloalkyl, C_3 to C_{10} cycloalkenyl, phenyl, naphthyl, (C_1 to C_{10} alkyl)phenyl, (C_2 to C_{10} alkenyl)phenyl, (C_1 to C_{10} alkyl) naphthyl, (C_2 to C_{10} alkenyl)naphthyl, phenyl(C_1 to C_{10} alkyl), phenyl(C_2 to C_{10} alkenyl), naphthyl(C_1 to C_{10} alkyl) and naphthyl(C_2 to C_{10} alkenyl);

R being optionally substituted with C_1 to C_{10} alkyl, C_2 to C_{10} alkenyl, C_1 to C_4 alkoxy, -OH, -SH, $-CO_2R^1$, C_3 to C_{10} cycloalkyl, C_3 to C_{10} cycloalkenyl, aryl, (C_1 to C_{10} alkyl)aryl, aryl(C_1 to C_{10})alkyl, or any combination thereof;

R being optionally interrupted by oxygen, nitrogen, sulfur, or any combination thereof; and

R^1 is hydrogen, C_1 to C_4 alkyl or C_2 to C_4 alkenyl; or

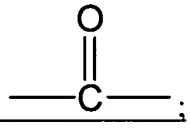
a salt thereof, and

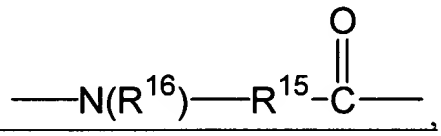
(b) an acylated amino acid having the formula having the formula:

$$Ar\text{-}Y\text{-}(R^{14})_n\text{-}OH$$

wherein:

Ar is a substituted or unsubstituted phenyl or naphthyl;

Y is  ;

R^{14} has the formula  ,

R^{15} is C_1 to C_{24} alkyl, C_2 to C_{24} alkenyl, phenyl, naphthyl, (C_1 to C_{10} alkyl) phenyl, (C_2 to C_{10} alkenyl) phenyl, (C_1 to C_{10} alkyl) naphthyl, (C_2 to C_{10} alkenyl) naphthyl, phenyl (C_1 to C_{10} alkyl), phenyl (C_2 to C_{10} alkenyl), naphthyl (C_1 to C_{10} alkyl), and naphthyl (C_2 to C_{10} alkenyl);

R^{15} is optionally substituted with C_1 to C_4 alkyl, C_1 to C_4 alkenyl, C_1 to C_4 alkoxy, -OH, -SH, $-CO_2R^{17}$, cycloalkyl, cycloalkenyl, heterocyclic alkyl, alkaryl, heteroaryl, heteroalkaryl, or any combination thereof;

R^{17} is hydrogen, C_1 to C_4 alkyl or C_2 to C_4 alkenyl;

R^{15} is optionally interrupted by oxygen, nitrogen, sulfur or any combination thereof; and

R^{16} is hydrogen, C_1 to C_4 alkyl or C_2 to C_4 alkenyl;

and n is from 1 to 5, or salt thereof.

Claim 110 (Currently Amended): A method as defined in claim 109, wherein said perturbant further comprises a pH changing agent, an ionic strength changing agent, or guanidine hydrochloride.

Claim 111 (Canceled).

Claim 112 (Currently Amended): The method of claim ~~128~~ 190, wherein the biologically active agent is human growth hormone.

Claim 113 (Currently Amended): The method of claim ~~128~~ 190, wherein the biologically active agent is growth-hormone releasing hormone.

Claim 114 (Currently Amended): The method of claim ~~128~~ 190, wherein the biologically active agent is insulin.

Claim 115 (Currently Amended): The method of claim ~~128~~ 190, wherein the biologically active agent is heparin.

Claim 116 (Currently Amended): The method of claim ~~128~~ 190, wherein the biologically active agent is low molecular weight heparin.

Claim 117 (Currently Amended): The method of claim ~~128~~ 190, wherein the biologically active agent is calcitonin.

Claim 118 (Currently Amended): The method of claim ~~128~~ 190, wherein the biologically active agent is cromolyn sodium.

Claim 119 (Currently Amended): The method of claim ~~128~~ 190, wherein the biologically active agent is an antimicrobial.

Claim 120 (Currently Amended): The method of claim ~~129~~ 191, wherein the biologically active agent is human growth hormone.

Claim 121 (Currently Amended): The method of claim ~~129~~ 191, wherein the biologically active agent is growth-hormone releasing hormone.

Claim 122 (Currently Amended): The method of claim ~~129~~ 191, wherein the biologically active agent is insulin.

Claim 123 (Currently Amended): The method of claim ~~129~~ 191, wherein the biologically active agent is heparin.

Claim 124 (Currently Amended): The method of claim ~~129~~ 191, wherein the biologically active agent is low molecular weight heparin.

Claim 125 (Currently Amended): The method of claim ~~129~~ 191, wherein the biologically active agent is calcitonin.

Claim 126 (Currently Amended): The method of claim ~~129~~ 191, wherein the biologically active agent is cromolyn sodium.

Claim 127 (Currently Amended): The method of claim ~~129~~ 191, wherein the biologically active agent is an antimicrobial.

Claims 128-130 (Canceled)

Claim 131 (Currently Amended): A method as defined in claim ~~130~~ 191, wherein the biologically active agent is an interferon.

Claim 132 (Currently Amended): A method as defined in claim ~~130~~ 191, wherein the biologically active agent is erythropoietin.

Claim 133 (Currently Amended): A method as defined in claim ~~130~~ 191, wherein the biologically active agent is an antigen.

Claim 134 (Currently Amended): A method as defined in claim ~~129~~ 191, wherein the biologically active agent is a peptide.

Claim 135 (Previously Presented): A method as defined in claim 134, wherein the biologically active agent is an interferon.

Claim 136 (Previously Presented): A method as defined in claim 134, wherein the biologically active agent is erythropoietin.

Claim 137 (Previously Presented): A method as defined in claim 134, wherein the biologically active agent is an antigen.

Claim 138 (Canceled):

Claim 139 (Currently Amended): The method of claim ~~138~~ 192, wherein the biologically active agent is human growth hormone.

Claim 140 (Currently Amended): The method of claim ~~138~~ 192, wherein the biologically active agent is growth-hormone releasing hormone.

Claim 141 (Currently Amended): The method of claim ~~138~~ 192, wherein the biologically active agent is insulin.

Claim 142 (Currently Amended): The method of claim ~~138~~ 192, wherein the biologically active agent is heparin.

Claim 143 (Currently Amended): The method of claim ~~138~~ 192, wherein the biologically active agent is low molecular weight heparin.

Claim 144 (Currently Amended): The method of claim ~~138~~ 192, wherein the biologically active agent is calcitonin.

Claim 145 (Currently Amended): The method of claim ~~138~~ 192, wherein the biologically active agent is cromolyn sodium.

Claim 146 (Currently Amended): The method of claim ~~138~~ 192, wherein the biologically active agent is an antimicrobial.

Claim 147 (Currently Amended): A method as defined in claim ~~138~~ 192, wherein the biologically active agent is a peptide.

Claim 148 (Previously Presented): A method as defined in claim 147, wherein the biologically active agent is an interferon.

Claim 149 (Previously Presented): A method as defined in claim 147, wherein the biologically active agent is erythropoietin.

Claim 150 (Previously Presented): A method as defined in claim 147, wherein the biologically active agent is an antigen.

Claim 151 (Canceled):

Claim 152 (Currently Amended): The method of claim ~~151~~ 193, wherein the biologically active agent is human growth hormone.

Claim 153 (Currently Amended): The method of claim ~~151~~ 193, wherein the biologically active agent is growth-hormone releasing hormone.

Claim 154 (Currently Amended): The method of claim ~~151~~ 193, wherein the biologically active agent is insulin.

Claim 155 (Currently Amended): The method of claim ~~151~~ 193, wherein the biologically active agent is heparin.

Claim 156 (Currently Amended): The method of claim ~~151~~ 193, wherein the biologically active agent is low molecular weight heparin.

Claim 157 (Currently Amended): The method of claim ~~151~~ 193, wherein the biologically active agent is calcitonin.

Claim 158 (Currently Amended): The method of claim ~~151~~ 193, wherein the biologically active agent is cromolyn sodium.

Claim 159 (Currently Amended): The method of claim ~~151~~ 193, wherein the biologically active agent is an antimicrobial.

Claim 160 (Currently Amended): A method as defined in claim ~~151~~ 193, wherein the biologically active agent is a peptide.

Claim 161 (Previously Presented): A method as defined in claim 160, wherein the biologically active agent is an interferon.

Claim 162 (Previously Presented): A method as defined in claim 160, wherein the biologically active agent is erythropoietin.

Claim 163 (Previously Presented): A method as defined in claim 160, wherein the biologically active agent is an antigen.

Claim 164 (Canceled):

Claim 165 (Currently Amended): The method of claim ~~164~~ 194, wherein the biologically active agent is human growth hormone.

Claim 166 (Currently Amended): The method of claim ~~164~~ 194, wherein the biologically active agent is growth-hormone releasing hormone.

Claim 167 (Currently Amended): The method of claim ~~164~~ 194, wherein the biologically active agent is insulin.

Claim 168 (Currently Amended): The method of claim ~~164~~ 194, wherein the biologically active agent is heparin.

Claim 169 (Currently Amended): The method of claim ~~164~~ 194, wherein the biologically active agent is low molecular weight heparin.

Claim 170 (Currently Amended): The method of claim ~~164~~ 194, wherein the biologically active agent is calcitonin.

Claim 171 (Currently Amended): The method of claim ~~164~~ 194, wherein the biologically active agent is cromolyn sodium.

Claim 172 (Currently Amended): The method of claim ~~164~~ 194, wherein the biologically active agent is an antimicrobial.

Claim 173 (Currently Amended): A method as defined in claim ~~164~~ 194, wherein the biologically active agent is a peptide.

Claim 174 (Currently Amended): A method as defined in claim 173, wherein the biologically active agent is an interferon.

Claim 175 (Currently Amended): A method as defined in claim 173, wherein the biologically active agent is erythropoietin.

Claim 176 (Currently Amended): A method as defined in claim 173, wherein the biologically active agent is an antigen.

Claim 177 (Canceled):

Claim 178 (Currently Amended): The method of claim ~~177~~ 195, wherein the biologically active agent is human growth hormone.

Claim 179 (Currently Amended): The method of claim ~~177~~ 195, wherein the biologically active agent is growth-hormone releasing hormone.

Claim 180 (Currently Amended): The method of claim ~~177~~ 195, wherein the biologically active agent is insulin.

Claim 181 (Currently Amended): The method of claim ~~177~~ 195, wherein the biologically active agent is heparin.

Claim 182 (Currently Amended): The method of claim ~~177~~ 195, wherein the biologically active agent is low molecular weight heparin.

Claim 183 (Currently Amended): The method of claim ~~177~~ 195, wherein the biologically active agent is calcitonin.

Claim 184 (Currently Amended): The method of claim ~~177~~ 195, wherein the biologically active agent is cromolyn sodium.

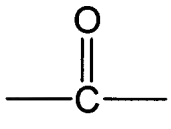
Claim 185 (Currently Amended): The method of claim ~~177~~ 195, wherein the biologically active agent is an antimicrobial.

Claim 186 (Currently Amended): A method as defined in claim ~~177~~ 195, wherein the biologically active agent is a peptide.

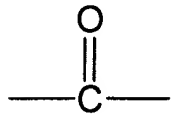
Claim 187 (Previously Presented): A method as defined in claim 186, wherein the biologically active agent is an interferon.

Claim 188 (Previously Presented): A method as defined in claim 186, wherein the biologically active agent is erythropoietin.

Claim 189 (Previously Presented): A method as defined in claim 186, wherein the biologically active agent is an antigen.

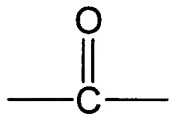
Claim 190 (New): A method as defined in claim 13, wherein said perturbant comprises an acylated amino acid in which Ar is substituted or unsubstituted phenyl, Y is  , R_{15} is C_1 to C_{24} alkyl, and n is equal to 1.

Claim 191 (New): A method as defined in claim 23, wherein said perturbant comprises an acylated amino acid in which Ar is substituted or unsubstituted phenyl, Y is



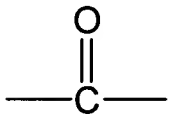
, R_{15} is C_1 to C_{24} alkyl, and n is equal to 1.

Claim 192 (New): A method as defined in claim 50, wherein said perturbant comprises an acylated amino acid in which Ar is substituted or unsubstituted phenyl, Y is



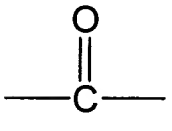
, R_{15} is C_1 to C_{24} alkyl, and n is equal to 1.

Claim 193 (New): A method as defined in claim 60, wherein said perturbant comprises an acylated amino acid in which Ar is substituted or unsubstituted phenyl, Y is



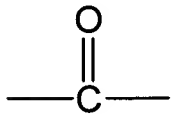
, R_{15} is C_1 to C_{24} alkyl, and n is equal to 1.

Claim 194 (New): A method as defined in claim 87, wherein said perturbant comprises an acylated amino acid in which Ar is substituted or unsubstituted phenyl, Y is



, R_{15} is C_1 to C_{24} alkyl, and n is equal to 1.

Claim 195 (New): A method as defined in claim 97, wherein said perturbant comprises an acylated amino acid in which Ar is substituted or unsubstituted phenyl, Y is



, R_{15} is C_1 to C_{24} alkyl, and n is equal to 1.